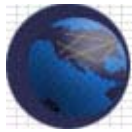


## Structured Protocol Representation SIG Teleconference, June 15, 2004

### Structured Protocol Representation SIG Teleconference

<b>Date, Time &amp; Location:</b>	June 15, 2004; 12:00-1:00 PM EDT; Teleconference		
<b>Attendees:</b>	<b>Center</b>	<b>Attendee</b>	
	COH	Joyce Niland	
	COH	Hemant Shah	
	Mayo Clinic	Sharon Elcombe	
	Memorial Sloan-Kettering	John Speakman	
	UC Irvine	Andrea Hwang	
	University of Pittsburg	Doug Fridsma	
	Wake Forest	Bob Morrell	
	NCI	Christo Andonyadis	
	NCI	Smita Hastak	
	BAH	Chalk Dawson	
	BAH	Davis Bu	
<b>Introduction:</b>	<ul style="list-style-type: none"> <li>Goals and scope</li> <li>Identify resources and previous work</li> <li>Schedule time for the next face to face meeting</li> </ul>		
<b>Goal and Scope:</b>	<ul style="list-style-type: none"> <li>Current environment at Centers: <ul style="list-style-type: none"> <li>Mayo has spent a fair amount of time trying to characterize protocols in their database</li> <li>Wake forest has organized database according to the protocol life cycle</li> <li>Types of data captured: Raw protocol data; administrative data; patient data</li> </ul> </li> <li>Importance of Structured Protocol Representations <ul style="list-style-type: none"> <li>Drives all other downstream activities</li> <li>May assist in development of template forms for standardized data collection by NCI</li> <li>Allows design of form in one place and have metadata used other places</li> <li>Facilitates classification of studies</li> </ul> </li> <li>Coordination with HL7 <ul style="list-style-type: none"> <li>HL7 Protocols Group: text based model, series of headers with textual information in the headers</li> <li>Not a computable representation, in part because pharmaceutical companies are not as focused in eligibility recruiting, but are more interested in human readable format for reporting</li> <li>HL7 Clinical Decision Support group much more focused on computable methods, e.g. exclusion criteria</li> <li>SIG should focus on computable representation</li> <li>HL7 protocol representation team meeting tomorrow, NCI will present use case for computable format</li> <li>City of Hope has use cases to make protocol representation drive all downstream activities, has models that are HL7 compliant</li> <li>SIG should develop models and CDEs to follow the HL7 RIM</li> <li>May model SIG activities around HL7: develop use cases -&gt; DMIM -&gt; data elements</li> <li>Initial use cases need not be fully fleshed out; may be made</li> </ul> </li> </ul>		



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	<ul style="list-style-type: none"><li>richer during development activities<ul style="list-style-type: none"><li>○ Would like our use cases to be accepted by HL7, but would proceed with development independent of HL7 timetable</li></ul></li><li>• Common datasets and issues raised<ul style="list-style-type: none"><li>○ Administrative data</li><li>○ Core protocol information</li><li>○ Reporting</li><li>○ Sharing</li><li>○ Computable representation</li><li>○ Data collection</li></ul></li><li>• Protocol life cycle<ul style="list-style-type: none"><li>○ UPMC has focused on protocol life cycle</li><li>○ May help to identify use cases</li><li>○ Life cycle of protocol will define scope of what we want to achieve</li></ul></li><li>• Use Cases<ul style="list-style-type: none"><li>○ Identifying use cases around functionality that does not exist today</li><li>○ Goal for SIG to collect and share existing use cases</li><li>○ Use cases will bound activities and existing tools should be leveraged</li><li>○ Identify strategic goals and timeline; begin goal setting</li></ul></li><li>• Standards and Harmonization<ul style="list-style-type: none"><li>○ Harmonization of use cases and data may be agenda item for future teleconference or face to face meeting</li><li>○ Standard and harmonization for codes may require interface with Vocabulary Working Group</li><li>○ One challenge may be to get centers to talk about same trials in the same way</li></ul></li><li>• Separable rules engine may allow flexibility</li><li>• SIG should strive for computable representation<ul style="list-style-type: none"><li>○ Flexible and updateable</li><li>○ Maintained over time as environment change</li><li>○ Utilize standard terminologies and data elements</li></ul></li><li>• Short term goal: Summary 4 Reporting</li></ul>
<b>Identification of Resources:</b>	<ul style="list-style-type: none"><li>• Goal is to have all systems to have common underlying framework to allow sharing</li><li>• One challenge is how to uniquely identify protocols</li><li>• CTEP, FDA, NCI, DCP, SPORES and other external drivers that need to be considered</li><li>• DCP mirrors well with CTEP system, although there is no current electronic interchange between the systems</li><li>• Smita Hastak to find out metadata structure CTEP, CTSU</li><li>• One goal may be to create metamodel to harmonize models across Centers and agencies</li><li>• Harmonize possible at domain level, but may be difficult at detailed</li></ul>

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	level			
<b>Future Meetings:</b>	<ul style="list-style-type: none"> <li>• Next meeting in two weeks</li> <li>• Additional items to discuss: <ul style="list-style-type: none"> <li>○ Identify use cases</li> <li>○ Report on existing resources to use</li> <li>○ Interaction with other vendors</li> <li>○ Further discussions of plans for face-to-face meetings</li> </ul> </li> <li>• June 29, 2004, 12:00-1:00 PM EDT pending confirmation lack of scheduling conflicts</li> </ul>			
<b>Action Items:</b>	<b>Name Responsible</b>	<b>Action Item</b>	<b>Date Due</b>	<b>Notes</b>
	All Participants	Current and future resource systems, drivers and use cases	Next SIG Teleconference	
	Smita Hastak	Make available data dictionaries (e.g. CTEP, CTSU)	Next SIG Teleconference	

Please list below and attach Meeting Materials and Agenda (if prepared separately):